

REMARKS

Claims 1 – 29 are currently pending. Claims 1 and 18 are the pending independent claims. In the Office Action, the Examiner rejected each of Claims 1 – 29 as allegedly obvious in view of U.S. Patent No. 6,359,011 to Bess et al. (“Bess”) taken in view of U.S. Patent No. 6,039,974 to MacLaren et al. (“MacLaren”) and U.S. Patent No. 5,738,872 to Ortyl et al. (“Ortyl”) and in further view of U.S. Patent No. 6,559,134 to Tanno et al. (“Tanno”).

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

Independent Claims 1 and 18 are directed to aspects of a bilayer tablet which includes, among other things, a first discrete portion which provides a sustained-release formulation of a sympathomimetic drug, such as pseudoephedrine and/or a pharmaceutically acceptable salt thereof, and a second discrete portion which provides an immediate-release formulation of a piperidinoalkanol and/or a pharmaceutically acceptable salt thereof, such as fexofenadine. In both Claims 1 and 18, the first discrete portion comprises a first carrier base providing the sustained release formulation for the sympathomimetic drug which includes, among other things, a cellulose binder selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, and mixtures thereof, wherein the hydroxypropyl cellulose has a molecular weight of at least 80,000, ethylcellulose, and from about 2 wt. % to about 50 wt. % of a wax selected from the group consisting of stearyl alcohol, cetyl alcohol, carnauba wax, white wax, yellow wax, microcrystalline wax, and mixtures thereof. None of the cited references, either alone or in combination, discloses or suggest a tablet composition of discrete bi-layers having these formulations for its parts.

Of the four cited references, only MacLaren discloses any form of bilayer tablet. Bess describes a single layer tablet comprising what is said to be a “denatured” sympathomimetic drug. Ortyl discloses a piperidinoalkanol in capsules, tablets, powders, and the like, but says nothing about a separate tablet layer for the sustained release of a sympathomimetic decongestant. Finally, Tanno discloses a rapidly disintegrating pharmaceutical composition, but says nothing about a separate tablet layer for the sustained release of a sympathomimetic drug.

While MacLaren does describe a two-part tablet with what is said to be a sustained release formulation for a sympathomimetic drug in one part and an immediate release

formulation for a piperidinoalkanol in another part, MacLaren says nothing about the inclusion of any hydroxypropyl binder in the sustained release, sympathomimetic drug part of the tablet together with ethyl cellulose as called for in Claims 1 and 18.

Further still, MacLaren specifies that the sustained release part of the tablet should have from 59 % to 81 %, by weight, carnauba wax. MacLaren teaches that this is needed to hold the parts of the tablet together. Over 50 wt. % carnauba wax is far more wax than the wax called for in Applicants' claims, which specify a total of no more than about 50% by weight of one or more of the listed waxes in the first part of the tablet. Thus, MacLaren teaches use of much greater amounts of wax than that specified in Applicants' Claims 1 and 18, and, therefore MacLaren would lead workers in the field away from the direction of Applicants' claimed compositions as a whole.

The denatured sympathomimetic compositions of Bess are devised to thwart nefarious attempts to convert sympathomimetic amine decongestants to "meth" and the like as a way of limiting illicit drug production. Bess has nothing to do with any bilayer tablet compositions geared toward providing both a slow or sustained-release decongestant part and a separate, quick-release antihistamine part. In fact, the Bess compositions have no antihistamine part at all. This is, of course, consistent with the focus of Bess to block attempts to convert certain decongestant compounds to illicit drugs by inclusion of materials said to act as "combination," "separation," or "reaction" inhibitors. No part of Bess teaches the claimed composition of a sustained or slow release sympathomimetic part in combination with an immediate release piperidinoalkanol part of a multi-functional tablet.

Furthermore, Bess is silent as to the inclusion of wax in any sympathomimetic composition, much less in any sympathomimetic part of a multi-layer, multi-functional tablet. Bess says nothing about the use of any of Applicants' claimed waxes, much less the claimed amounts. Thus, even if a person of ordinary skill were attempting to somehow combine the teachings of MacLaren and Bess, and there is no reason why they would, they still would have incorporated from 59 to 81 wt. %, carnauba wax in the sympathomimetic part, not about 2 to 50 wt. % of one or more of the waxes called for by Applicants in Claims 1 and 18.

The mere fact that Bess mentions the possible use of cellulose derivatives in a "denatured" sympathomimetic formulation would not have lead a person of ordinary skill to attempt to incorporate them into a new bilayer tablet according to Applicant's claims.

MacLaren notes at length in his background that others have attempted to combine sympathomimetic drugs, such as pseudoephedrine, with a piperidinoalkanol, such as fexofenadine, in the past. According to MacLaren, attempts to make two-part sympathomimetic/ piperidinoalkanol tablets have generally failed due to unacceptable cracking and lack of physical strength. See MacLaren. Col. 1, line 60 – Col. 2, line 13. Given these past failures, and seeing that MacLaren purports to have solved the “strength” problems, etc. by using large amounts of carnauba wax in the sympathomimetic part and a special mixture of materials in the second part, no person of ordinary skill would have been led to deviate from MacLaren’s teachings and go “back to the drawing board” vis-à-vis sympathomimetic part to make multi-layer tablets with cellulosic derivatives in the sympathomimetic part of the tablet, and less than 50 wt.% wax. Such a modification would run counter to the entire basis of the improvement said to be afforded by MacLaren’s use of over 50 wt. % carnauba wax in the first part of the tablet to confer structural integrity. Such a modification cannot be said to be “obvious.”

There is nothing in the art of MacLaren, Bess, or any of the other references to suggest combining them to make multi-layer tablet formulations according to Applicants’ claims. MacLaren explicitly denounces prior bi-layer tablet formulations having a sustained or slow release decongestant part and a physically separate quick release antihistamine part as having poor physical properties, and purports to solve these problems by incorporating more than 50 wt.% carnauba wax in the first part containing the decongestant material. Bess’s so-called “denatured” decongestant formulations suggest no modification to MacLaren’s alleged improved bi-layer tablet composition containing over 50% carnauba wax in the sympathomimetic part for strength purposes. Even if a person of skill chose to add Bess’s “cocktail” of “combination inhibitors,” “reaction inhibitors,” and/or “separation inhibitors” to MacLaren’s “waxy” bi-layer tablet, and there is nothing to suggest they would, there is no discernable reason why incorporating Bess’s array of alleged inhibitors into the decongestant part of MacLaren’s two-part tablet would alter MacLaren’s teaching to use over 50 wt. % carnauba wax in this part of the tablet to supposedly keep the tablet from falling apart. Such a composition is far from what Applicants are claiming.

It is illogical to assume Bess’s various “inhibitors” would somehow be added into MacLaren’s bi-layer tablet while sacrificing MacLaren’s alleged “strengthening” attributes

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from the inclusion of over 50 wt. % carnauba wax. While there is no reason to suppose a person of skill would try to combine any of these references to make Applicants' composition, even if they did try to combine the references in some fashion, Bess applied to modify MacLaren would, at most, add one or more of these alleged inhibitors of Bess to MacLaren's sympathomimetic part for inhibiting illicit drug manufacture from the active ingredient, while retaining MacLaren's over 50 wt. % carnauba wax for what is said to be necessary for sufficient strength properties. That is, it would not be logical or "obvious" to modify the MacLaren tablet in such a way as to destroy its utility for intended consumer use. Any "non obvious" modification of MacLaren after Bess's teachings would still be expected to retain the 50 wt.%(plus) carnauba wax to keep the tablets from falling apart according to what MacLaren said was necessary.

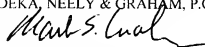
In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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